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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/561,339 | 12/19/2005 | Kevin T. Hogan | 00914-03 | 5928 |
| 34444 7590 10/16/2007 UNIVERSITY OF VIRGINIA PATENT FOUNDATION 250 WEST MAIN STREET, SUITE 300 CHARLOTTESVILLE, VA 22902 | | | EXAMINER DAVIS, MINH TAM B | |
| | | | ART UNIT 1642 | PAPER NUMBER |
| | | | MAIL DATE 10/16/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,339

Applicant(s)

HOGAN ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 16-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-15 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of Group 19, claims 13-15, SEQ ID NO:1 in the reply filed on 08/24/07 is acknowledged.

The traversal is on the following ground(s):

1. The nucleic acids SEQ ID Nos: 2-5 of groups 20-23, claims 13-15 should be rejoined with the nucleic acid SEQ ID NO:1 of group 19, because they share a common 196 bases at the 5' end of the five sequences

This is not found persuasive, because although SEQ ID No:1 has in common with SEQ ID Nos: 2-5 a fragment consisting of nucleotides 1-196 of SEQ ID NO:1, said fragment is, however, is not a contribution over the art, as shown by DOE Joint Genome Institute and Stanford Human Genome Center, Feb,15,2002 (MPSRCH search result, 2007, 10.561.339.1.Oligo.rge, pages 1-2). According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art.

MPSRCH search result, 2007, 10.561.339.1.Oligo.rge, pages 1-2.

RESULT 6
AC106771/c
LOCUS AC106771 172930 bp DNA linear PRI 15-FEB-2002
DEFINITION Homo sapiens chromosome 5 clone RP11-308B16, complete sequence.
ACCESSION AC106771
VERSION AC106771.2 GI:18677374
KEYWORDS HTG.
SOURCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini; Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 172930)
AUTHORS DOE Joint Genome Institute and Stanford Human Genome Center.
TITLE Direct Submission
JOURNAL Unpublished

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REFERENCE 2 (bases 1 to 172930)
 AUTHORS DOE Joint Genome Institute.
 TITLE Direct Submission
 JOURNAL Submitted (12-JAN-2002) Production Sequencing Facility, DOE Joint Genome Institute, 2800 Mitchell Drive, Walnut Creek, CA 94598, USA

REFERENCE 3 (bases 1 to 172930)
 AUTHORS DOE Joint Genome Institute and Stanford Human Genome Center.
 TITLE Direct Submission
 JOURNAL Submitted (15-FEB-2002) DOE Joint Genome Institute, 2800 Mitchell Drive, Walnut Creek, CA 94598, USA

COMMENT On Feb 15, 2002 this sequence version replaced gi:18139321.
 Draft Sequence Produced by DOE Joint Genome Institute
 www.jgi.doe.gov
 Finishing Completed at Stanford Human Genome Center
 www-shgc.stanford.edu
 Quality: Phrap Quality >=40 99.9% of Sequence;
 Estimated Total Number of Errors is 0.1.

FEATURES Location/Qualifiers
 source 1. .172930
 /organism="Homo sapiens"
 /mol_type="genomic DNA"
 /db_xref="taxon:9606"
 /chromosome="5"
 /clone="RP11-308B16"

ORIGIN

Query Match 100.0%; Score 196; DB 5; Length 172930;
 Best Local Similarity 100.0%; Pred. No. 6.1e-113;
 Matches 196; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 CTCCACACCGCCTTGCAAGCTGAGGGAGCCGGCTCCGGCCTCTGCCAGCCCAGGAAGGGG 60
 |||
 Db 106569 CTCCACACCGCCTTGCAAGCTGAGGGAGCCGGCTCCGGCCTCTGCCAGCCCAGGAAGGGG
 106510

Qy 61 CTCCCACAGTGCAGCGGCGGGCTGAAGGACTCCTCAAGTGCCACCAAAGTGGGAGCCCAG 120
 |||
 Db 106509 CTCCCACAGTGCAGCGGCGGGCTGAAGGACTCCTCAAGTGCCACCAAAGTGGGAGCCCAG
 106450

Qy 121 GCAGAGGAGGCGCCGAGAGCGAGCGAGGGCTGCCTGCCAGCACGCTGTCACGTCTCAGCA 180
 |||
 Db 106449 GCAGAGGAGGCGCCGAGAGCGAGCGAGGGCTGCCTGCCAGCACGCTGTCACGTCTCAGCA
 106390

Qy 181 ATAGACTGCTCTTGAG 196
 |||
 Db 106389 ATAGACTGCTCTTGAG 106374

2. Group 1, claims 1-7, 23-25, and 27 should be rejoined with SEQ ID NO:1 of

group 19, because the polypeptide SEQ ID NO:6 is encoded by the nucleic acid SEQ ID NO:1 of

group 19, and because Example 17 of Annex B provides that a protein and a DNA sequence encoding it share unity.

This is not found persuasive, because Example 17 of Annex B does not apply here. The peptide of claims 3-4 of group 1, of about 15 amino acids, and comprising an amino acid sequence identical to 9 amino acids of SEQ ID NO:6, comprises an extra five amino acids with unknown structure, and thus is **not encoded by SEQ ID NO:1**, which is a full length sequence. It is noted that Example 17 represents **a single species of a protein** and a genus of nucleic acids, which encode the protein.

3. The amino acid sequences SEQ ID NO:7-11, 22-24 of groups 2-9 should be rejoined with the polypeptide SEQ ID NO:6 of group 1, because SEQ ID Nos: 6-11 all share a 39 amino acid sequence, and SEQ ID NOs:22-24 share the first 11 amino acids with SEQ ID Nos: 6-11.

This is not found persuasive, because although SEQ ID Nos: 6-11 all share a 39 amino acid fragment, and SEQ ID NOs:22-24 share the first 11 amino acids with SEQ ID Nos: 6-11, there is no indication that said fragment alone confers the biological function of the nucleic acid SEQ ID NO:1 encoding SEQ ID NO:6, which is not even disclosed in the specification.

4. Group 35, drawn to a method for detecting cancer, using SEQ ID NO:1 should be rejoined with group 19, drawn to SEQ ID NO:1, for reasons set forth above. Additionally, groups 36-39, drawn to a method for detecting cancer using SEQ ID Nos: 2-5 should be rejoined with group 35 and also group 19, for reasons set forth above.

This is not found to be persuasive, because group 19 is not rejoined with group 1, for reasons set forth above. Further, only the first group, group 1, has a combination of a product, the

first method of use and the first method of making. All other products and methods will be broken out as separate groups (see CFR 1.475(d)).

5. Groups 40-47, claims 23-25, 27, drawn to a method for detecting cancer, by detecting the peptides SEQ ID Nos: 7-11, and 22-24 should be rejoined with group 19 and group 1 for reasons set forth above.

This is not found to be persuasive, because group 19 is not rejoined with group 1, for reasons set forth above. Further, only the first group, group 1, has a combination of a product, the first method of use and the first method of making. All other products and methods will be broken out as separate groups (see CFR 1.475(d)).

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, group 19, claims 13-15, SEQ ID NO:1, are examined in the instant application.

The embodiments of claims 13-15, as drawn to SEQ ID Nos: 2-5 have been withdrawn from consideration as being drawn to non-elected invention.

Claims 13-15, as drawn to the nucleic acid SEQ ID NO:1 (TAG-1), are allowable, because SEQ ID NO:1 is overexpressed in various cancer tissues as compared to normal corresponding tissues (table 3 on page 37 and table 4 on page 39), and is free of prior art.

Specification

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The specification is objected to, because the legends of figures 1-2 on page 5 do not correspond with the content of the drawing.

Conclusion

Claims 13-15 are allowable, if they were amended to delete the non-elected sequences SEQ ID Nos: 2-5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MINH TAM DAVIS
September 12, 2007

/Larry R. Helms/
Supervisory Patent Examiner